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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,794	02/01/2001	Norman G. Anderson	41039	2626

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EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/774,794	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> Nelson Yang	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16, 18, 22-24 and 81-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 82 and 83 is/are allowed.
- 6) ☒ Claim(s) 16, 18, 22-24, 81 and 84-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of claim 16 is acknowledged and has been entered.
2. Claims 16, 18, 22-24, and 81-87 are currently pending.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants do not disclose that the proteins are immobilized in or on different fibers without denaturing the proteins in the specification.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 16, 18, 22-24, and 81 rejected under 35 U.S.C. 102(e) as being anticipated by Borrelli et al [US 6,350,618].

With respect to claims 16, 18, 22-24, and 81, Borrelli et al teach a method of making an array of biological samples comprising the steps of providing a device having a plurality of open ended channels extending from an input face to an output face wherein at least along a length, each channel decreases approximately equally in diameter, cross sectional area, and wall thickness; filling a plurality of said channels with a liquid that is capable of hardening under proper conditions, whereby said liquid contains a biological material such as proteins (column 11, line 8); allowing said liquid to harden; slicing a section of said device such that said sliced section becomes the array (claim 1); and then bonding the sliced section to a substrate (claim 2). Borrelli also disclose an embodiment where biomolecules are attached to beads which fit one at a time through the output of any individual channel as a means to immobilize the biomolecules (column 16, lines 36-45). These channels can be a bundle of capillary tubes (column 9, lines 18-28). Each sliced section is 4-10 microns in thickness (claim 5).

7. With respect to claims 86, 87, Borrelli et al further teach that each channel can be filled with a liquid consisting of a different mixture of a particular binding entity and a thermally activated curing polymer such as an epoxy resin (column 16, lines 58-60), where each channel contains 2-10  $\mu$ L of printable liquid (column 15, lines 40-45)

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 84, 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borrelli et al [US 6,350,618] in view of Walt et al [US 6,377,721] and further in view of Attridge et al [US 5,478,755].

Borrelli et al teach a method of making an array of biological samples comprising the steps of providing a device having a plurality of open ended channels extending from an input face to an output face wherein at least along a length, each channel decreases approximately equally in diameter, cross sectional area, and wall thickness; filling a plurality of said channels with a liquid that is capable of hardening under proper conditions, whereby said liquid contains a biological material; allowing said liquid to harden; slicing a section of said device such that said sliced section becomes the array (claim 1); and then bonding the sliced section to a substrate (claim 2). These channels can be a bundle of capillary tubes (column 9, lines 18-28). Borrelli et al also disclose an embodiment where biomolecules are attached to beads which fit one at a time through the output of any individual channel, and uses this means to immobilize the biomolecules (column 16, lines 36-45). Borrelli et al further teach that this process may be utilized with any material that can either polymerize, bond to the channel interior walls, or is capable of being frozen and cut (column 17, lines 55-60). Borrelli et al do not specifically teach biological cells or microorganisms.

Walt et al, however, do teach the use of cells in fiber optic arrays. Walt et al further teach that the characteristics of an entire cell population as a whole can be studied with bulk measurements of sample volumes having a plurality of cells (column 2, lines 32-49). Walt et al further teach that the selectivity of living cells has considerable value and utility in drug screening and analysis of complex biological fluids (column 5, lines 35-55).

Attridge et al further teach that that antibodies can bind antigens to the wall of a capillary cavity (column 6, line 65 – column 7, line 15), where the antigens can be cells (column 7, lines 65-67). Therefore, the method of Borrelli et al can be modified so as to include cells.

Therefore it would have been obvious in the method of Borrelli for the biomolecules to be biological cells, as taught by Walt et al, by modifying the method according to Attridge et al, in order to utilize the selectivity of living cells in drug screening and analysis of complex biological fluids.

### ***Double Patenting***

10. Claims 16, 18, 81, 84, 85, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,713,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent recites a method for making an array that encompasses all the steps recited in the instant claims.

11. Claim 22, 24, 85, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7 of U.S. Patent No. 6,846,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent recites an array that encompasses all the limitations recited in the instant claims.

### ***Response to Arguments***

12. Applicant's arguments filed May 12, 2005 have been fully considered but they are not persuasive. Applicant argues that the methods such as hydrocarbons, epoxy polymerization, divinyl benzene linking, and ethylene glycol, acrylamide polymerization would denature the

proteins. Even if this were true, Borrelli also disclose an embodiment where biomolecules are attached to beads which fit one at a time through the output of any individual channel, and uses this means to immobilize the biomolecules (column 16, lines 36-45).

Applicant further argues that the temperatures needed to melt glass or polymers denature or degrade proteins. However, the glass is melted to form the channels (column 9, lines 1-12), to which the proteins are added. Furthermore, Borrelli disclose alternative embodiments that do not require heating the glass, such as bonded capillary tubes (column 9, lines 45-50).

13. This is also applicable to applicant's arguments regarding claim 84.

14. Applicant further argues that many of the chemicals used are toxic to living cells.

Applicant's arguments are noted, but as was discussed above, Borrelli also disclose an embodiment that is not toxic to the cells. Furthermore, the claim does not require that the cells be alive, as long as the fixed position of the cells with respect to each other is maintained. It should also be pointed out the combination of references used teaches an alternative way to immobilize the cells.

With respect to applicant's statement that the present invention was optimized with maintaining proteins in mind, it is unclear what applicant's argument is, as the claim appears to be directed toward immobilizing biological cells or microorganisms. Furthermore, Borrelli et al do teach that proteins can be used in the invention. If applicant was referring to cells or microorganisms instead of proteins, it should be noted that Borrelli specifically

15. With respect to applicant's arguments regarding claim 86 that Borrelli does not teach channels with same agent of interest but at different concentrations, it should be pointed out that Borrelli teaches that each channel may have between 2 to 10  $\mu$ L of printable liquid, which

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translates into approximately between 20,000 and 100,000 drops of 80pl/drop (column 15, lines 40-45). Therefore, the concentration between any two channels in the array would indeed vary.

16. Applicant's arguments regarding the obviousness-double patenting rejection have been acknowledged.

### *Conclusion*

17. Claims 82, 83 are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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07/25/05